

REMARKS

Claim Status

Claims 1-2, and 6-45 are pending in this application and new Claims 46-47 added. Of these, Claims 6-40 have been withdrawn from consideration and Claims 1 and 2 are amended herein. Support for the new claims can be found, *inter alia*, in lines 11-29, pg. 11 of the specification.

Rejection under 35 U.S.C. §112, 2nd ¶

Claim 2 is rejected under 35 U.S.C. §112, second paragraph, as being unclear with respect to how the detection channel is “defined” in the claimed apparatus. Without commenting on the propriety of the rejection and with an interest in expediting prosecution, Applicant has removed the word “defined” from Claim 2. Withdrawal of the rejection is therefore respectfully requested.

Rejection under 35 U.S.C. §102

Claims 1-2 and 41-45 are rejected under 35 U.S.C. §102(e) as being anticipated by Buechler (US 2002/0086436). Applicant respectfully traverses this rejection for the following reasons and in view of the foregoing amendments.

Under 35 U.S.C. §102, a claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The present invention is directed to a device with “a carrier formed of a permeable material for conducting flow of liquid sample.” See presently amended Claim 1. On the contrary, Buechler’s devices “do not use bibulous or porous materials, such as membranes and the like as substrates for the immobilization of reagents or to control the flow of the reagents through the device.” As such, Applicant respectfully submits that the present invention is novel in view of Buechler’s disclosure given its failure to teach every element of the claim. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §103

Claims 1-2 and 41-45 are rejected under 35 U.S.C. §103(a) as being obvious over Buechler (US 2002/0086436). Applicant respectfully traverses this rejection for the following reasons.

In the post-KSR landscape, it remains improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). While Applicants acknowledge that Buechler’s devices employ capillary channels as Examiner

noted, those of ordinary skill in the art would not understand Buechler's devices to be "of a permeable material" as presently claimed. In Buechler's efforts to circumvent problems associated with membranes, *e.g.* differential properties, susceptibility to non-specific binding, reproducibility issues, uneven flow of assay reagents, *etc.*, he opted instead to use "defined surfaces, all of which are constructed from non-absorbent materials." See [0029] and [0031] of Buechler. Note that Paragraph 135 of Buechler also proposes modifying conventional devices by swapping out and substituting various porous members with components having defined impermeable surfaces, such as time gates, fluid control means, channels, sample reaction barrier with fingers, and reaction chamber, which culminates in teaching further away from the present invention.

Under MPEP 2141.02(VI), prior art must be considered in its entirety, including disclosures that teach away from the claims. One of ordinary skill in the art, being informed by Buechler of the many ills associated with membrane carriers, would be discouraged from using a permeable carrier and encouraged to swap out as many porous components as feasible from conventional assay designs. As such, the cited reference provides no motivation to modify Buechler's design and arrive at the present invention. Furthermore, the proposed modification would render the prior art unsatisfactory for its intended purpose, *i.e.* to avoid the problems associated with porous members in assay devices, and violate the holding of *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). See MPEP 2143.01(V), stating that "no suggest or motivation to make the proposed modification" exists where the "proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose."

Even assuming *arguendo* that motivation exists, "the teachings of the references are not sufficient to render the claims *prima facie* obvious" where "the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified." See *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) and MPEP 2143.01(VI). As noted in Col. 3, lines 21-35 of the specification, the present invention is premised in part on the discovery that the particular relationship between the width of the detection channel and sample band sample flow can be manipulated to direct sample flow towards and into the detection channel, concentrate reagent-bound analyte at the entry to the detection channel, and enhance assay sensitivity. The above phenomenon can be induced on "a carrier of a permeable material" as clearly detailed by the instant disclosure. Buechler, however, aims to avoid differential flow problems which he associates with the use of porous or absorbent members and adopts a different mechanism, *e.g.* chambers, capillary channels, grooves with defined water-impermeable surfaces, for conveying the sample from one end of his structure to another.

As such, the present invention is not rendered *prima facie* obvious by Buechler and withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Should the Examiner have any continuing objections, the Applicants respectfully ask the Examiner to contact the undersigned at 415-442-1490 (direct line) in order to expedite allowance of the case. Authorization is granted to charge any outstanding fees due at this time for the continued prosecution of this matter to Morgan, Lewis & Bockius LLP Deposit Account No. 50-0310 (matter no. 054468-5011-US01).

Respectfully submitted,

Date:

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